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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,775	07/19/2001	Susan Schiavi	GZ 2065.23	2672

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EXAMINER

GIBBS, TERRA C

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 09/25/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,775

Applicant(s)

SCHIAVI ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 6-14 and 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

This Office Action is a response to the Amendment filed June 24, 2003 in Paper No. 20.

Claims 1-20 are pending. Claims 1-4, 6-14 and 16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 16.

Priority

It is noted that the previous Office Action, filed March 26, 2003 made a statement that the reference to priority in the first line of the Specification should be updated with current serial numbers where patents have issued. It is noted that this statement was an error on the Examiner and this statement is not applicable to the instant application.

Information Disclosure Statement

The Supplemental IDS filed March 11, 2003 in Paper No. 19 is acknowledged.

Response to Amendment

Specification

The specification was objected to because the specification contained embedded hyperlinks and/or other forms of browser-executable code. This objection is withdrawn in view of Applicants Amendment.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5 and 15 were objected under 35 U.S.C., 112, second paragraph for reciting the term "FRP-4 protein". This rejection is withdrawn in view of Applicants Amendment.

Claim Rejections - 35 USC § 112

Claim 5 was rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is withdrawn in view of Applicants Amendment to the claims to include mammalian frizzled-related prtein-4.

Claims 5 and 15 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is withdrawn in view of Applicants Arguments and Applicants submission of a copy of their manuscript accepted for publication, which discloses *in vivo* data showing that FRP-4 protein infusions increased renal fractional excretion of inorganic phosphate and decreased serum phosphate.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Erding et al. [EP 0879,881].

Claim 5 is drawn to a method of reducing phosphate re-absorption in a subject comprising the delivery of a mammalian frizzled-related protein-4.

Erding et al. disclose the delivery of a therapeutically effective amount of a human ATG-1639 polypeptide to a subject for the treatment of diseases (see Abstract and pages 11 and 12, for example). Erding et al. disclose the human ATG-1639 polypeptide as SEQ ID NO:2 (see Erding et al. SEQ ID NO:2). The ATG-639 polypeptide of Erding et al. is 99.5% identical to human frizzled-related protein-4 (SEQ ID NO:2) of the instant invention. Since the ATG-1639 polypeptide of Erding et al. is 99.5% identical to a mammalian frizzled-related protein-4, the delivery of the ATG-1639 polypeptide of Erding et al. in a subject would inherently reduce phosphate re-absorption as claimed in the instant invention.

The instant claims and Erding et al. provide the same level of guidance and therefore are enabled to the same extent. Therefore, Erding et al. anticipate claim 5.

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Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Lark et al. [EP 0877,406].

Lark et al. disclose the delivery of a therapeutically effective amount of a human FRAZZLED polypeptide to a subject for the treatment of diseases (see Abstract and pages 16 and 17, for example). Lark et al. disclose the human FRAZZLED polypeptide as SEQ ID NO:2 (see Lark et al. SEQ ID NO:2). The PRAZZLED polypeptide of Lark et al. is 99.3% identical to human frizzled-related protein-4 (SEQ ID NO:2) of the instant invention. Since the FRAZZLED polypeptide of Lark et al. is 993% identical to a mammalian frizzled-related protein-4, the delivery of the FRAZZLED polypeptide of Lark et al. in a subject would inherently reduce phosphate re-absorption as claimed in the instant invention.

The instant claims and Lark et al. provide the same level of guidance and therefore are enabled to the same extent. Therefore, Lark et al. anticipate claim 5.

Conclusion

Claim 15 is objected to because it is dependent on a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg

September 17, 2003


KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER